

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

2:16 MD 1203

3. Matrix Benefits are paid according to two benefit matrices  
(continued...)

To seek Matrix Benefits, a representative claimant<sup>4</sup> must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician who must answer a series of questions concerning the deceased's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, the attorney for the representative claimant must complete Part III if claimant is represented.

In January, 2002, the Estate submitted a completed Green Form to the Trust signed by the attesting physician, Kenneth B. Desser, M.D., F.A.C.P., F.C.C.P., F.A.C.C., F.A.H.A. Based on a Report of Autopsy dated April 6, 2000 and a Report of

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3. (...continued)  
(Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § 11.B.

Cardiac Pathology Consultation dated June 5, 2000,<sup>5</sup> Dr. Desser attested in Part II of the Green Form that Mr. Rosenberg suffered from endocardial fibrosis.<sup>6</sup> In a handwritten statement on the Green Form, Dr. Desser explained:

This subject had a cardiac arrest which was fatal. At autopsy there was calcific aortic stenosis, interstitial myocardial fibrosis, left ventricular hypertrophy, thickening of the mitral valve, myxomatous degeneration of the tricuspid valve, left ventricular endocardial fibrosis and incidental eosinophilic myocarditis[.]

In the Report of Autopsy completed by James Gill, M.D., the final diagnoses included degenerative calcific aortic stenosis with cardiac hypertrophy and hypertensive cardiovascular disease with moderate-marked arteriolosclerosis. In the Report of Cardiac Pathology Consultation completed by Barbara Sampson, M.D., Ph.D., the gross and microscopic diagnoses included degenerative calcific aortic stenosis, cardiac hypertrophy, thickening of the mitral valve, and eosinophilic myocarditis (incidental). Dr. Sampson wrote:

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5. Although the Estate did not submit an echocardiogram for Mr. Rosenberg, a representative claimant is eligible to receive Matrix Benefits when the Diet Drug Recipient is diagnosed by a Qualified Physician as having endocardial fibrosis on or before September 30, 2005 and either the Diet Drug Recipient or the representative claimant registered for benefits on or before January 31, 2006. See Settlement Agreement § IV.B.1.e.

6. Dr. Desser also attested that Mr. Rosenberg suffered from a reduced ejection fraction in the ranges of 35% to 39%, 40% to 49%, and 50% to 60%, and died from a condition caused by VHD. These conditions, however, are not at issue in this claim.

GROSS DESCRIPTION:

... The three aortic valve cusps are thickened and moderately calcified and the right and left commissure are fused. (Comment: This most likely represents a congenital defect of the valve with secondary, degenerative calcification.) There is slight endocardial fibrosis of the left ventricle inferior to the aortic valve.

MICROSCOPIC DESCRIPTION:

There is a marked myocyte hypertrophy with patchy interstitial and perivascular fibrosis. A few small foci of mixed inflammatory cells ... and dying myocardium are most consistent with microscopic areas of ischemia/infarct with ongoing healing. One very small focus consists predominantly of eosinophils with associated myocyte damage ... (comment: consistent with an incidental focus of eosinophilic myocarditis) .... There is nonspecific degeneration of the mitral and aortic valves. The aortic valve is moderately fibrotic.

Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits in the amount of \$886,662.<sup>7</sup>

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7. Under the Settlement Agreement, a claimant is entitled to Level V Matrix Benefits if he or she suffers endocardial fibrosis diagnosed by: (1) an endomyocardial biopsy that demonstrates fibrosis and cardiac catheterization that demonstrates restrictive cardiomyopathy; or (2) an autopsy that demonstrates endocardial fibrosis. See Settlement Agreement § IV.B.2.c.(5)(a). In addition, a claimant must show that other causes, including dilated cardiomyopathy, myocardial infarction, amyloid, Loeffler's endocarditis, endomyocardial fibrosis as defined in Braunwald, focal fibrosis secondary to valvular regurgitation (e.g., "jet lesions"), focal fibrosis secondary to catheter instrumentation, and hypertrophic cardiomyopathy with septal fibrosis, have been excluded. See id. As the Trust concedes that Mr. Rosenberg had endocardial fibrosis, the only issue is whether the "other causes" of endocardial fibrosis have been excluded as required by the Settlement Agreement.

On July 2, 2002, the Trust advised the Estate that its claim had been selected for audit.<sup>8</sup> In response, the Estate submitted a letter from Dr. Desser, in which he stated that Mr. Rosenberg met the criteria under the Settlement Agreement for endocardial fibrosis. Specifically, Dr. Desser noted that: (1) the Certificate of Death indicated that myocardial infarction and aortic regurgitation were not primary or secondary causes of death; (2) the gross description of the heart "revealed endocardial fibrosis of the left ventricle inferior to the aortic valve" and Mr. Rosenberg did not have atherosclerotic disease or myocardial ischemia or infarction; and (3) the assumption that the sub-aortic fibrosis was caused by a "jet" lesion was unsupported because there was no clinical evidence of aortic regurgitation.

In August, 2002, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Desser's finding that other

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8. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified myocardial infarction and focal fibrosis secondary to valvular regurgitation as other causes of endocardial fibrosis that had not been excluded. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

causes of the decedent's endocardial fibrosis had been excluded.

In a certification, Dr. Irani stated that:

Autopsy specifically mentions areas of myocardial [sic] infarction with aortic stenosis with secondary left ventricular hypertrophy.

I have reviewed the amended records regarding Mr. Rosenberg's case. While it is true that aortic regurgitation was not mentioned on the death certificate, it is not unlikely that a patient with severe aortic stenosis may have aortic regurgitation. Unfortunately, there is no documentation of an imaging study being performed. In light of the fact that the aortic stenosis went undetected it would not be surprising that a regurgitant murmur may have been undetected.

Overall, I do not believe that one can assume the fibrosis is not due to regurgitation simply because it was not demonstrated. The presumption that fibrosis was due to diet drugs requires an assumption without the ability to completely exclude a regurgitant lesion and thus I do not believe that all other causes of endocardial fibrosis have been excluded.

Based on the auditing cardiologist's finding that other causes of endocardial fibrosis had not been excluded, the Trust issued a post-audit determination denying the Estate's claim. Pursuant to the Audit Policies and Procedures, the Estate contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and Procedures § IV.C.<sup>9</sup> The Trust then applied to

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9. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO (continued...)

the court for issuance of an Order to show cause why the Estate's claim should be paid. On January 2, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2690 (Jan. 2, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on March 26, 2003, and the Estate submitted a sur-reply on April 10, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor<sup>10</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show

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9. (...continued)

No. 2457. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to the Estate's claim.

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for the attesting physician's finding of endocardial fibrosis with other causes of endocardial fibrosis having been excluded. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Estate's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of its claim, the Estate raises the same arguments it made in response to the Audit Selection Letter, namely, that Dr. Desser diagnosed Mr. Rosenberg as having endocardial fibrosis and that Dr. Desser excluded as causes myocardial infarction and aortic insufficiency. The Estate also submitted a letter from Carman H. Brooks, M.D., F.R.C.P."C", F.A.C.C., in which Dr. Brooks stated:

The autopsy shows interstitial fibrosis and cardiovascular inflammation. I do not believe that Mr. Rosenberg had a myocardial infarction. The distribution of the pathologic changes is not that of myocardial infarction and/or ischemia. Secondly, I do not believe that Mr. Rosenberg had insufficient valvular pathology, which would cause the endocardial fibrosis in this



particular situation. Valvular insufficiency causes ventricular dilation which was not present.

In addition, the Estate argues that Dr. Irani applied an incorrect standard when evaluating its claim. According to the Estate, Dr. Irani required claimant to show that Mr. Rosenberg's ingestion of Diet Drugs caused his endocardial fibrosis. The Estate further contends that neither myocardial infarction nor focal fibrosis secondary to valvular regurgitation was referenced in the cardiac pathology and that Dr. Irani simply adopted Wyeth's position that reference to a "'small healing ischemic injury'" in the pathology report "was synonymous with 'myocardial infarction.'" Finally, the Estate asserts that the Trust prejudiced the audit process because it did not submit to Dr. Irani for consideration during his initial review the Estate's additional supporting documentation.<sup>11</sup>

In response, the Trust argues that the Estate failed to meet its burden as its claim "is based on a presumption that other causes of endocardial fibrosis have been excluded simply because the pathology report and Mr. Rosenberg's medical history do not mention other causes." According to the Trust, a claimant cannot meet his or her burden by relying on presumptions that medical conditions were not present.

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11. We disagree. In a letter to the Trust following his initial review, and in the Certification of Auditing Cardiologist, Dr. Irani stated specifically that he "reviewed the amended records regarding Mr. Rosenberg's case."

In its sur-reply, the Estate argues that the Trust should not be allowed to deny its claim based on the failure of the Report of Cardiac Pathology Consultation to exclude specifically other causes of endocardial fibrosis. The Estate asserts that "medical records, autopsies, and pathology records are both a record of the conditions the Claimant does have and a record of the conditions the patient does not have." (emphasis in original). According to the Estate, neither the Report of Autopsy nor the Report of Cardiac Pathology Consultation diagnosed Mr. Rosenberg with myocardial infarction or "'other causes'" of endocardial fibrosis, and, thus, there was a reasonable medical basis for the attesting physician's finding that other causes of endocardial fibrosis had been excluded.

The Technical Advisor, Dr. Vigilante, reviewed the record and determined that there was no reasonable medical basis for the attesting physician's finding that all other causes of the decedent's endocardial fibrosis have been excluded. Specifically, Dr. Vigilante concluded that other causes existed including myocardial infarction, hypertrophic cardiomyopathy, Loeffler's endocarditis, and focal fibrosis secondary to valvular regurgitation. As explained by Dr. Vigilante:

It is documented on the gross description of the cardiac pathology consultation report that "there is slight endocardial fibrosis of the left ventricle inferior to the aortic valve." However, the other enumerated causes mentioned in question L6 were not excluded as causes of endocardial fibrosis. Specifically, myocardial infarction would need to have been excluded. In fact, on

microscopic description, there was the finding of "a few small foci of mixed inflammatory cells ... and dying myocardium are most consistent with microscopic areas of ischemia/infarct with ongoing healing." Indeed, Dr. Sampson did diagnose myocardial infarction and stated so in her microscopic description. In addition, the claimant did have hypertrophic cardiomyopathy as documented on the certificate of death. The endocardial fibrosis of the left ventricle inferior to the aortic valve found on autopsy would include the base of the septum found immediately below the aortic valve. Therefore, hypertrophic cardiomyopathy with septal fibrosis has not been excluded. In addition, "an incidental focus of eosinophilic myocarditis was found." This finding is also noted in Loeffler's endocarditis. In addition, the large majority of patients with aortic stenosis have some degree of aortic insufficiency. Therefore, focal fibrosis secondary to valvular regurgitation also has not been excluded as a cause of endocardial fibrosis.

Significantly, as part of his review, Dr. Vigilante was asked to determine whether each of the other causes of endocardial fibrosis was reflected on the Report of Autopsy. In response, Dr. Vigilante stated that:

[I]t was noted on the autopsy report that he had aortic stenosis, hypertrophic cardiomyopathy, an area of eosinophilic myocarditis, and areas of myocardial infarct.

In summary, although Mr. Gene Rosenberg had slight endocardial fibrosis of the left ventricle inferior to the aortic valve, other causes of this condition as described in the green form have certainly not been excluded.

In response to the Technical Advisor Report, the Estate asserts that "[t]he Technical Advisor is holding Claimant to an unduly high burden not contemplated by the terms of the

Settlement Agreement." The Estate also takes issue with Dr. Vigilante's conclusion that, depending upon the situation, other causes, if present, would be observed and recorded in an autopsy report or an endomyocardial biopsy report. According to the Estate, Dr. Vigilante's findings require a claimant to "'rule out' conditions that even an autopsy and cardiac pathology have not identified." Finally, the Estate notes that "nowhere prior to the Technical Advisor's Report had anyone contended that Mr. Rosenberg had 'hypertrophic cardiomyopathy with septal fibrosis,'" and that the condition does not appear anywhere in Mr. Rosenberg's medical history.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. As previously stated, a claimant is entitled to Level V Matrix Benefits if he or she has:

Endocardial Fibrosis (1) diagnosed by  
(a) endomyocardial biopsy that demonstrates fibrosis and cardiac catheterization that demonstrates restrictive cardiomyopathy or  
(b) autopsy that demonstrates endocardial fibrosis and (2) other causes, including dilated cardiomyopathy, myocardial infarction, amyloid, Loeffler's endocarditis, endomyocardial fibrosis as defined in Braunwald (involving one or both ventricles, located in the inflow tracts of the ventricles, commonly involving the chordae tendineae, with partial obliteration of either ventricle commonly present), focal fibrosis secondary to valvular regurgitation (e.g., "jet lesions"), focal fibrosis secondary to catheter instrumentation, and hypertrophic cardiomyopathy with septal fibrosis, have been excluded.

Settlement Agreement § IV.B.2.c.(5)(a). Here, despite the Estate's assertion that it should be permitted to rely on Mr. Rosenberg's medical records to establish the absence of other causes, Dr. Vigilante specifically identified in his review of the medical records four "other causes" of Mr. Rosenberg's endocardial fibrosis. Although Dr. Desser and Dr. Brooks responded to two of the causes addressed by the Trust - myocardial infarction and focal fibrosis secondary to valvular regurgitation - the Estate did not address Dr. Vigilante's finding that additional "other causes" of endocardial fibrosis identified in the records had not been excluded by the attesting physician. Specifically, the Estate failed to address Dr. Vigilante's finding that Mr. Rosenberg's endocardial fibrosis may have been caused by: (1) "'an incidental focus of eosinophilic myocarditis,'" a finding also noted in "Loeffler's endocarditis"; and (2) "hypertrophic cardiomyopathy with septal fibrosis." Each of these conditions is specifically listed as "other causes" required under the Settlement Agreement to be excluded. See Settlement Agreement § IV.B.2.c.(5)(a). On this basis alone, the Estate has failed to meet its burden.

We also disagree with the Estate that Dr. Vigilante's determination that these other causes exist purportedly requires claimant to "'rule out' conditions that even an autopsy and cardiac pathology have not identified." Dr. Vigilante, however, specifically found that the Report of Autopsy and the Report of

Cardiac Pathology Consultation identified four "other causes."<sup>12</sup> Accordingly, the Estate must exclude these "other causes" to receive Matrix Benefits. Under these circumstances, the Estate has not met its burden in proving a reasonable medical basis for excluding "other causes" of endocardial fibrosis.

For the foregoing reasons, we conclude that the Estate has not met its burden in proving that there is a reasonable medical basis for finding that the decedent had endocardial fibrosis with other causes of endocardial fibrosis having been excluded. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix Benefits and the related derivative claims submitted by Mr. Rosenberg's spouse and child.

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12. For this reason as well, we disagree with claimant that Dr. Irani used an inappropriate standard to evaluate the Estate's claim.